Gift ban costing state medical jobs

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The Massachusetts law designed to prevent pharmaceutical and medical device firms from having undue influence on doctors is spurring job losses at local companies and research institutions, industry insiders claim.

The so-called gift ban went into effect in July, and since then medical device companies have been scrambling to understand and comply with the bill. Enforcement activities will not start until this July, after companies file their first yearly reports. But the threat of running afoul of the law — which prohibits companies from giving doctors gifts, entertainment and most meals — has driven companies to curtail sales, marketing and training activities in Massachusetts. Some outside companies are avoiding Massachusetts altogether.

The result is fewer jobs related to training, medical device sales and clinical trials.

"It's put a real chill on Massachusetts' doctors opportunities to take part in training and clinical research on medical devices," said Dr. Carey Kimmelstein, a cardiologist at **Tufts Medical Center**.

Boston cardiologists regularly participated in a series of trainings that were funded by medical device companies. Those have completely stopped, Kimmelstein said. The purpose of the trainings was to update heart doctors on the newest procedures, and unusual cases.

Doctors were not paid to participate, and Kimmelstein said they often didn't even know which company was funding the training. The problem is that it's now illegal to provide doctors with meals outside of a hospital setting, and with hospital meeting space in short supply, many such trainings take place in restaurants.

Kimmelstein said he has seen the impact of the bill at medical device companies, where sales people have lost jobs, and at peer medical institutions, where fewer trials means less need for research staff.

Kimmelstein sits on a few medical advisory boards for device firms, a common way for doctors to provide feedback on new devices. He said some companies have made it clear they now won't be asking Massachusetts doctors to join their boards. He said he has recently not been invited to networking meetings to discuss potential collaborations on trials because they may involve meals.

"Some of the regulations have caused medical device companies to twist like a pretzel to comply with the law," said Seth Lundy, deputy chairman of the life sciences practice at King and Spaulding law firm in Washington, D.C. He said one problem is that the new law

requires medical device companies to have a signed agreement for a doctor to purchase a device before providing training. But it's often hospitals — and not doctors — who hold the purse strings, so some of Lundy's clients have had to invent soft contracts stating a doctor's desire to purchase the device.

Lundy and other lawyers and consultants say that their small medical device clients have in some cases decided not to do business in Massachusetts, rather than file onerous paperwork. They would not disclose the names of the companies due to confidentiality agreements.

Eric Lawson, a partner at Voisin Consulting based in Cambridge, said that one of his medical device clients from out of state typically runs pilot programs with a small group of doctors before launching a full-fledged clinical trial.

"They said they are going to stop doing this in Massachusetts, because it's too difficult and too expensive to do all the necessary reporting," Lawson said.

Several medical device companies, inside as well as outside of Massachusetts, either declined to comment for this article or did not respond to repeated calls for comment.

"I'm not surprised companies did not want to talk about this," said Tom Sommer, president of MassMedic, the state industry organization for medical device companies. Sommer said there is still a significant amount of confusion over the law, and the organization held a panel Friday with regulators and attorneys, to help clear up lingering questions.

State regulators say they plan to go easy on inadvertent violations of the law in the first year. "But if we see anything egregious, we are going to go after that," said Elizabeth Daake, director of policy development, planning and research at the <u>Massachusetts</u>

<u>Department of Public Health</u>. Each infraction carries up to a \$5,000 penalty.

One fear about the gift ban law has not materialized. Jim Rooney, executive director of the **Massachusetts Convention Center Authority**, said that while the authority lost a few pieces of business they were competing for, there has not been a significant drop off in medical convention business, which accounts for over 40 percent of all Massachusetts conventions.

But, he said, "we had to spend a lot of time with show producers from out of state, explaining the bill to them."

The biggest hit could be to the state's reputation as a cutting edge center for medical technology.

"Boston is known as a hotbed of innovation, and the reluctance of companies to work with Massachusetts doctors is a concern. Companies are increasingly turning to states like Texas and California for researchers, where there are no similar regulations," Lundy said.